



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/613,795

07/02/2003

Guy Vanney

2097/US

7349

33486

7590

10/03/2006

HEIMBECHER & ASSOC., LLC

P O BOX 33

HAMEL, MN 55340-0033

EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/613,795

Applicant(s)

VANNEY, GUY

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3 and 5-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, and 5-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received August 11, 2006, have been fully considered by the examiner. In particular, applicant's amendments have obviated the 35 USC 112, second paragraph issues. The following is a complete response to the August 11, 2006 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1, 3 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Brucker et al (5,462,521).

Brucker et al disclose a catheter ablation apparatus that includes a tubular body (22) having a manifold (distal tip 50 of Figure 9). Ablation fluid (i.e. saline) flows through the manifold, and the manifold comprises an inlet port (60 – Figure 9) in communication with a fluid supply (54) and an outlet port (58) in communication with the inlet port and having a larger dimension than the inlet port. The entire tip member (50) is an electrode and is therefore in the ablation fluid path. The examiner maintains that the enlarged opening (58) relative to the inlet path would inherently provide a swirling of the fluid, and either of the “x” or “y” axis in Figure 9 could be deemed the “longitudinal axis” to thereby meet the limitations of claims 2 and 3. The electrode (50) is housed in an electrode lumen (28) of the catheter (22), and the electrode lumen (28) is in fluid communication with the outlet ports. The manifold further includes a channel (54) that is in fluid communication with the outlet port, the channel also being located within the channel (28) in the catheter.

Claims 1, 3, and 5-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Swartz et al (6,080,151).

As shown in Figure 10, Swartz et al provide an ablation catheter including a tubular body (300) having a manifold (304) in the body. The manifold includes a plurality of inlet ports (306) that communicate with exit ports (310), whereby the exit ports are larger than the inlet ports. Swartz et al disclose inlet and outlet ports in the size limitations set forth in claim 5 (see col. 7, lines 65-67 and col. 11, lines 7-16). Manifold (304) includes an electrode (302) housed in a lumen of the catheter, and there is a channel extending into the manifold (304) for delivering fluid through the inlet ports (306).

Claim Rejections - 35 USC § 103

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al ('151) in view of the teaching of Bednarek et al ('500).

Swartz et al, as addressed previously, fail to specifically show a curved catheter tip. In as much as the Swartz et al catheter is used in cardiac procedures, it is presumably flexible and able to be placed in arcuate positions to treat tissue. However, to further illustrate that it is known to provide such a catheter with an arcuate shape to treat cardiac tissue, attention is directed to Bednarek et al.

The Bednarek et al device is substantially identical to the Swartz et al device and is used in treating cardiac tissue (just as the Swartz et al catheter is used). In particular,

Bednarek et al teach that it is known to provide the catheter with an arcuate distal shape (Figure 2) to facilitate placement at certain cardiac locations.

To have provided the Swartz et al device with an arcuate distal section to facilitate the catheter's placement at desired cardiac locations would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Bednarek et al.

Response to Arguments

Applicant's arguments filed August 11, 2006 have been fully considered but they are not persuasive.

With regard to the Brucker reference, applicant contends that the Brucker reference fails to disclose providing a "swirling motion" of the fluid and that the examiner's assertion of inherency is not properly supported. Applicant further indicates that Paragraph 0069 of the specification provides the support for the swirling motion. It is noted that Paragraph 0069 of the printed publication (2005/0004565) provides the support indicated by applicant, but for some unforeseen reason that same paragraph is numbered 0067 in the specification as filed in the Image File Wrapper in the Office.

The examiner maintains that sound technical reasoning supports the assertion that the Brucker reference would inherently provide fluid having a "swirling motion". Basic fluid dynamics would dictate that any fluid flowing from an orifice would exhibit some level of turbulence. That is, laminar flow from a nozzle is not possible. Turbulence is defined as the creation of circular, or "eddy" currents in the fluid flow, which the examiner maintains is a reasonable definition of a "swirling motion". With

regard to applicant's assertion on page 6 of the response that paragraph 0069 describes that the angle of entry of the inlet port produces the swirling, the examiner points out that the angle of entry is used to create a "swirling vortex", and such a specific swirling motion is not recited in the claims as presented. Rather, the claims merely call for a "swirling motion", and the examiner maintains that this broader limitation may be interpreted to include the eddy current motions that would inherently be present in a fluid discharged from an opening as in the Brucker device.

The examiner agrees with applicant's characterization of the Brucker outlet port as being a "slot" cut into the electrode. However, applicant has not defined the shape of the outlet port in the claims. Again, the examiner maintains that any fluid emitted from the Brucker ports would inherently have some degree of turbulence, as simple fluid mechanics would dictate, and that this turbulence may be fairly interpreted to be a "swirling motion" as set forth in the claims.

With regard to the Swartz reference, the examiner again agrees with applicant's characterization of Swartz as providing a uniform distribution of fluid. However, the examiner again maintains that fluid flowing from a port will inherently have a turbulent flow, which turbulent flow may be interpreted as having a "swirling motion". The turbulence may be minimal, however, there is nothing in applicant's claims which defines the amount or type of the swirling motion.

Applicant's amendments to claim 12 have obviated the 35 USC 102 rejections involving the Tu and Bednarek references. Also, applicant's arguments with respect to

the 35 USC 103 rejection of claim 5 as being obvious over Brucker in view of Swartz are persuasive and that ground of rejection has been withdrawn.

Concerning claim 12, applicant has asserted that neither Swartz nor Bednarek teach a port that provides a swirl to the ablation fluid. For the reasons presented earlier, the examiner maintains that both of these references would inherently provide a fluid flow having a swirling motion. Applicant has not argued the validity of combining the Bednarek teaching of providing a probe with an arcuate shape, and the examiner maintains that the teaching would clearly suggest that such a shape may be provided to the Swartz device as asserted in the body of the rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

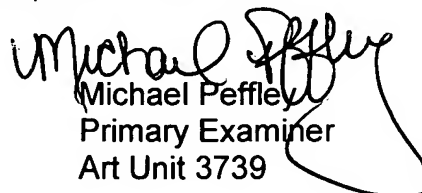
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3739

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
September 20, 2006